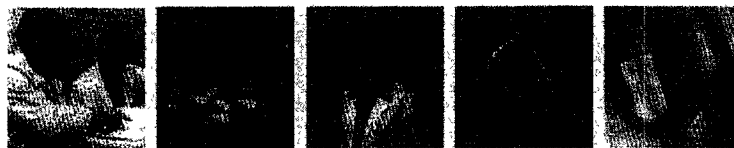


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# EXHIBIT 31



## Helping Members Respond to Problems with the Supply of Quality Pharmaceuticals



Problems with the nation's drug supply—drug shortages, errors by compounding pharmacies, and counterfeiting—have greatly affected the quality of care offered to patients in hospitals and health systems. ASHP is leading efforts to combat these problems, including collaborations with other health care organizations and advocacy before federal and state legislators and regulators. The Society has also developed several resources to assist members in facing these practice challenges so that valuable pharmacy resources can be directed toward taking care of patients.

### Managing Drug Product Shortages

The increased prevalence of drug shortages is an ongoing problem, particularly as the volume of drugs in short supply has risen dramatically in the last four years. Helpful strategies for responding to a drug shortage include:

1. Visit the ASHP Drug Shortages Resources Center regularly to get updates on the status of drug shortages and read updates on recommended therapeutic alternatives ([www.ashp.org/shortage](http://www.ashp.org/shortage)). Additional information can be obtained from the FDA Web site ([www.fda.gov/drug/shortages/default.htm](http://www.fda.gov/drug/shortages/default.htm)) or the CDC Web site ([www.cdc.gov](http://www.cdc.gov)).
2. Develop policies on how to deal with shortages, preferably guided by a medical staff committee or some other governing body. Policies should include a plan to communicate information about the shortage, how patients will be prioritized, and how decisions will be made about preferred therapeutic alternatives.
3. Consider establishing a multidisciplinary committee when there needs to be ongoing pharmacy, nursing and medical staff involvement around a drug or group of drugs in short supply.
4. Don't underestimate the importance of educating staff about a drug shortage, especially when an alternative treatment is being substituted. Errors can occur when caregivers have a new drug with different dosing and side effects than what they are accustomed.
5. Communicating the status of shortages to caregivers is critical. Treatment decisions can be made more effectively when the prescriber knows what options are available.
6. Each shortage should be evaluated for its expected duration. Techniques used to manage the shortage will vary greatly depending on whether it is short term (1-2 weeks) or long term (4 weeks or more).
7. Short term strategies might include rationing, communicating with health professionals, and searching for additional supplies. Longer term strategies will likely require broader and sustained communication, identifying therapeutic alternatives, and more aggressive steps, such as developing policies and procedures for handling shortages.

### Tips for Working with a Compounding Pharmacy

Shortages of commercially available injectable drug products have forced hospital and health-system pharmacists to consider purchasing compounded preparations from compounding pharmacies, especially when alternative commercial products are not available or acceptable. The pharmacy director or pharmacist-in-charge is legally responsible for the quality of purchased compounded preparations and the safety of patients for whom the preparations might be obtained. Recent reports of injectables contaminated with microbes and the resultant patient harm are a reminder that due diligence is necessary to ensure patient safety. Before a sterile preparation is obtained from a compounding pharmacy, the following questions should be considered:

1. What are the regulations for using compounded preparations in the state where the purchasing institution is located?
2. Does the institution get informed consent from patients before using a compounded preparation from an outside source?
3. Does the institution inform health care professionals (e.g., prescribers, nurses) that a compounded preparation from an outside source will be used, including the possible risks associated with its use?

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4. Does the compounding pharmacy use USP-grade raw material?
5. What is the source of the raw material (if animal, domestic or imported)?
6. Is every batch of raw material, if from an animal source, screened for viral contamination?
7. Is every batch of the compounded preparation tested for quality and compliance with standards published in the USP compendia?
8. What sterilization process is used for the packaging and the final preparation?
9. Is every batch of preparation quarantined for more than ten days?
10. Is every batch of preparation tested for sterility on days two and ten?
11. Is every batch of preparation tested for pyrogens on day ten?
12. Has the compounding pharmacy performed extended stability tests?
13. For each batch of preparation made, does the compounding pharmacy provide a "beyond-use" date after which it should not be used?

### Strategies to Protect Against Drug Counterfeiting

The increased presence of counterfeit drug products poses significant dangers to the safety of the medication-use process. Here are some strategies that pharmacists can take to lower the probability of unintentionally acquiring counterfeit products:

1. Contact your primary wholesaler and inquire about their anti-counterfeiting measures and sources of product. Make sure your suppliers are taking steps to limit their sources of products to authorized manufacturers and authorized distributors.
2. Check the FDA Web site (<http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm>) at least weekly for new reports of counterfeit products detected in the pharmaceutical supply chain.
3. Check your group purchasing organization (GPO) Web site for reports of counterfeit products.
4. Contact your board of pharmacy, department of health, or other appropriate state agency periodically to determine whether there are problematic wholesalers in your state. Links to these web sites can be found at: <http://www.nabp.org>.
5. Limit or eliminate the use of secondary distributors unless you can verify that they are an authorized distributor purchasing from authorized manufacturers and are in good standing with your state board of pharmacy or other licensing agency. Verify that they are in compliance with the HDMA Voluntary Guidelines for Pharmaceutical System Integrity, which are available at <http://www.healthcaredistribution.org>.
6. Re-evaluate pharmacy department security measures to minimize risk of diversion or entry of counterfeit products.
7. Pay particular attention to products considered to be at 'high risk' for counterfeiting. Be mindful that expensive drug products and drugs in short supply are more likely to be counterfeited than other medications. Common drugs found to be targeted by counterfeiters include anti-retrovirals, epoetin alfa, filgrastim, somatropin, and sildenafil.
8. Educate all pharmacy staff about counterfeiting, what they should look for, and how to report a suspicious product. Provide additional training and instruction to the staff persons responsible for ordering and/or receiving products from distributors. Alert clinical and staff pharmacists to consider a counterfeit product as a possible reason for an unusual adverse drug reaction or unusual response to a medication.
9. Consider how nurses, medical staff, and patients should be alerted to the potential for counterfeit products. Review policies for medication acquisition with your Pharmacy and Therapeutics Committee to ensure that necessary controls are in place.
10. Take comments and complaints about products seriously and investigate them promptly. Many counterfeit products were discovered only after patients complained of a change in effectiveness or a change in taste of their oral medications.
11. If you encounter a questionable product, contact the manufacturer or wholesaler to determine how the product authenticity should be verified. Counterfeit products should be reported to the FDA through the MedWatch program (<http://www.fda.gov/medwatch/>) or at 800-332-1088.

#### Additional Resources:

- **Drug Shortages:** <http://www.ashp.org/shortage/index.cfm>
- **Sterile Compounding:** <http://www.ashp.org/bestpractices/Chapter797-SterileCompounding.pdf>
- **Counterfeiting:** <http://www.ashp.org/practicemanager/ASHPAnti-counterfeitingStrategies.pdf>